

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISION

KEVIN C. SEARCY, as Personal Representative and Administrator of the Estate of Isaiah Searcy, deceased,	)
	)
Plaintiff,	)
	)
v.	)      CASE NO. 2:23-cv-750-ECM
	)                    [WO]
PFIZER, INC., <i>et al.</i> ,	)
	)
Defendants.	)

**MEMORANDUM OPINION and ORDER**

**I. INTRODUCTION**

This case arises out of the death of Isaiah Searcy (“Isaiah”), who died after receiving a COVID-19 vaccine. Kevin Searcy, the administrator of Isaiah’s estate (“Plaintiff” or “Estate”), brought this action in Alabama state court, and it was removed to this Court on December 29, 2023. A key dispute is whether the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d (“PREP Act”), bars the Estate’s claims.

In the second amended complaint (“SAC”) (the operative complaint), the Estate has sued the following Defendants: Pfizer, Inc. and BioNTech (the “Pfizer Defendants”); Baptist Health, Baptist Medical Center South, Baptist Medical Center East, and Montgomery Baptist Hospital (the “Baptist Health Defendants”); and the Department of Defense,<sup>1</sup> the Department of Health and Human Services (“HHS”), Robert F. Kennedy,

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<sup>1</sup> The Court acknowledges that the Department of Defense is now the Department of War. Because it was the Department of Defense when this action was filed, the Court will refer to it as such in this Opinion.

Jr., Secretary of HHS,<sup>2</sup> and Pete Hegseth, the Secretary of Defense<sup>3</sup> (the “Federal Defendants”) (collectively, the “Defendants”). (Doc. 127). The Secretary of HHS and the Secretary of Defense are sued in their official capacities. The Estate seeks compensatory and punitive damages, a declaration that the PREP Act is unconstitutional, and for the Court to enjoin the PREP Act.

Now pending before the Court are motions to dismiss filed by the Federal Defendants (doc. 132), the Pfizer Defendants (doc. 133), and the Baptist Health Defendants (doc. 135). The motions are fully briefed and ripe for review. After carefully reviewing the parties’ submissions and the applicable law, and for the reasons that follow, the Court concludes that the motions to dismiss are due to be granted.

## **II. JURISDICTION AND VENUE**

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1442(a)(1).<sup>4</sup> Personal jurisdiction and venue are uncontested, and the Court concludes that venue properly lies in the Middle District of Alabama. *See* 28 U.S.C. § 1391.

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<sup>2</sup> The Clerk of the Court is DIRECTED to correct the docket to reflect that Robert F. Kennedy, Jr., Secretary of HHS, is a Defendant in this case.

<sup>3</sup> Pete Hegseth is now the Secretary of Defense and is automatically substituted as a party under Federal Rule of Civil Procedure 25(d) for former Secretary of Defense Lloyd J. Austin, III. Accordingly, the Clerk of the Court is DIRECTED to correct the docket to reflect this change.

<sup>4</sup> If a civil action is commenced in state court against “[t]he United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, in an official or individual capacity, for or relating to any act under color of such office,” then the civil action may be removed to federal district court. 28 U.S.C. § 1442(a)(1). The Estate brought this case in the Circuit Court of Montgomery County, Alabama, against a federal agency (the Department of Defense), a federal officer (the Secretary of Health and Human Services), and against persons “acting under” a federal officer (the Pfizer Defendants). The Pfizer Defendants initiated the removal, (doc. 1), and the Federal Defendants joined in it, (doc. 1-7 at 2). Consequently, because a federal agency and a federal officer removed the case, this Court has jurisdiction pursuant to § 1442(a)(1). Alternatively, removal was proper because the Pfizer Defendants have established they were “acting under” the Secretary’s authority when they manufactured

### III. LEGAL STANDARD

A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint against the legal standard set forth in Rule 8: “a short and plain statement of the claim showing that the pleader is entitled to relief.” FED. R. CIV. P. 8(a)(2). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). At this stage of the proceedings, “the court must accept as true all factual allegations in the complaint and draw all reasonable inferences in the plaintiff’s favor.” *Bailey v. Wheeler*, 843 F.3d 473, 478 n.3 (11th Cir. 2016).

“Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679. The plausibility standard requires “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* at 678. Conclusory allegations that are merely “conceivable” and fail to rise “above the speculative level” are insufficient to meet the plausibility standard. *Twombly*, 550 U.S. at 555–56. This pleading standard “does not require ‘detailed factual allegations,’ but it demands more than an

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COVID-19 vaccines pursuant to government contracts; a causal connection exists between the Estate’s claims and the Pfizer Defendants’ actions taken under color of federal office; and the Pfizer Defendants raise colorable federal defenses (PREP Act immunity and preemption). *See Caver v. Cent. Ala. Elec. Coop.*, 845 F.3d 1135, 1142–46 (11th Cir. 2017); *see also Caratini-Soto v. Puerto-Rico*, 2023 WL 11196890, at \*3 (D.P.R. Dec. 28, 2023) (concluding that Pfizer properly removed, pursuant to § 1442(a)(1), an action in which the plaintiff sought to hold Pfizer liable for injuries stemming from COVID-19 vaccines which Pfizer had developed and manufactured “pursuant to government contracts to aid the federal government’s response to the pandemic”). The Estate has not challenged the propriety of the removal to this Court.

unadorned, the-defendant-unlawfully-harmed-me accusation.” *Iqbal*, 556 U.S. at 678 (citation omitted). Indeed, “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’” *Id.* (citation omitted).

#### **IV. BACKGROUND**

##### **A. Statutory and Regulatory Background**

In 2005, Congress enacted the PREP Act, Pub. L. No. 109-148, 119 Stat. 2680, Division C (2005) (codified at 42 U.S.C. §§ 247d-6d, 247d-6e), to encourage the development and use of medical countermeasures in response to or in anticipation of public health emergencies. *See* Cong. Rsch. Serv., Compensation Programs for Potential COVID-

19 Vaccine Injuries 2 (updated Oct. 20, 2021),

<https://crsreports.congress.gov/product/pdf/LSB/LSB10584> (last visited Sept. 17, 2025).

The PREP Act authorizes the Secretary of HHS (“Secretary”) to determine that a disease, “other health condition,” or “other threat to health” is a “public health emergency,” or poses a “credible risk” of a future emergency. 42 U.S.C. § 247d-6d(b)(1). If the Secretary makes such a determination, the Secretary “may make a declaration”—hereinafter referred to as a “PREP Act declaration”—“recommending . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures.” *Id.* “Covered countermeasures” include “qualified pandemic or epidemic products,” *id.* § 247d-6d(i)(1), which are drugs, biological products, or devices that are manufactured, used, designed, or developed “to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic” or “to limit the harm such pandemic or epidemic might otherwise cause.” *Id.* § 247d-6d(i)(7).

The Act requires the Secretary to include certain information in the PREP Act

declaration, including the specific disease, health condition, or threat to health triggering the Secretary’s recommendation; when the declaration is in effect, which “may be designated by dates, or by milestones or other description of events”; and to which individuals the declaration applies and where. *Id.* § 247d-6d(b)(2). And within thirty days of issuing a PREP Act declaration, the Secretary must submit a report to “the appropriate committees of the Congress” explaining his or her reasons for issuing the declaration and for deciding the timeframe, geographical scope, and other criteria set forth in § 247d-6d(b)(2). *Id.* § 247d-6d(b)(9). The Secretary may amend a PREP Act declaration through publication in the Federal Register. *Id.* § 247d-6d(b)(4). And like the initial declaration, the Secretary must submit a report to Congress within thirty days of the amendment explaining the reasons for it. *Id.* § 247d-6d(b)(9).

Pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”), the Secretary may also authorize emergency use of medical products to diagnose, treat, or prevent a life-threatening disease or condition if he or she determines that circumstances exist justifying such authorization. *See* 21 U.S.C. § 360bbb-3(a)–(c). The Secretary may issue an Emergency Use Authorization (“EUA”) for a medical product if he or she concludes that several statutory criteria are satisfied, including that a public health emergency has been declared involving an agent that can cause “a serious or life-threatening disease or condition”; “the product may be effective in diagnosing, treating, or preventing . . . such disease or condition”; and “there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition.” *Id.* § 360bbb-

3(c). The Secretary’s actions relating to emergency use authorizations are “committed to agency discretion.” *Id.* § 360bbb-3(i).

If the Secretary issues a PREP Act declaration, then “covered persons” are “immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). A “covered person” means the United States; a manufacturer, distributor, or program planner of a covered countermeasure; a “qualified person who prescribed, administered, or dispensed such countermeasure”; or “an official, agent, or employee” of one of the aforementioned categories. *Id.* § 247d-6d(i)(2). Although the United States is a “covered person,” *id.*, the PREP Act does not waive federal sovereign immunity or “abrogate or limit any defense or protection available to the United States,” *id.* § 247d-6d(f). The PREP Act also expressly preempts all state laws and state “legal requirement[s]” that differ from or conflict with the Act and “relate[] to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure.” *Id.* § 247d-6d(b)(8).

But the PREP Act does not leave aggrieved persons without a remedy. First, it provides a “willful misconduct” exception to PREP Act immunity. *See id.* § 247d-6d(d)(1) (explaining that the “sole exception” to PREP Act immunity “shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury

proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person”). The “willful misconduct” standard, as defined in § 247d-6d(c)(1)(A), “establish[es] a standard for liability that is more stringent than a standard of negligence in any form or recklessness.” *Id.* § 247d-6d(c)(1)(B). Further, the Act requires willful misconduct claims to be brought in the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1). But the Act excludes regulated activity of a manufacturer or distributor from the definition of willful misconduct. Specifically, the Act provides that “an act or omission by a manufacturer or distributor with respect to a covered countermeasure . . . shall not constitute ‘willful misconduct’ . . . if . . . neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission.” *Id.* § 247d-6d(c)(5)(A).

An aggrieved person may also, in certain circumstances, bring a claim for compensation from the federal government through an administrative claims process. *See* 42 U.S.C. § 247d-6e; 42 C.F.R. § 110.1. The PREP Act established “an emergency fund designated as the ‘Covered Countermeasure Process Fund’” (“CCPF”) to compensate “eligible individuals for covered injuries” caused by a covered countermeasure. *See* 42 U.S.C. § 247d-6e(a). A “[c]overed [i]njury” means death or “serious injury” that is “the direct result of the administration or use of a covered countermeasure.” *See* 42 C.F.R. § 110.3(g). The Countermeasures Injury Compensation Program (“CICP”) administers the CCPF through a no-fault claims process. *See id.* § 110.1. Claims must be filed within one year of the date of administration of the vaccine or other covered countermeasure. *See* 42 U.S.C. § 247d-6e(b)(4) (incorporating the procedures stated in 42 U.S.C. § 239a); *id.*

§ 239a(d) (setting forth the one-year deadline); *see also* 42 C.F.R. § 110.42(a), (d) (setting forth a one-year deadline for filing claims).

In March 2020, the Secretary issued a PREP Act declaration regarding the COVID-19 pandemic. *See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198 (Mar. 17, 2020). The declaration defined a covered countermeasure to include “any vaccine[] used to treat, diagnose, cure, prevent, or mitigate COVID-19.” *Id.* at 15,202. Additionally, the Secretary issued an EUA declaration “declar[ing] that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic.” *See Emergency Use Authorization Declaration*, 85 Fed. Reg. 18,250, 18250–51 (Apr. 1, 2020).

On December 11, 2020, the FDA granted an EUA for the Pfizer-BioNTech COVID-19 vaccine. Pfizer-BioNTech entered into a federal government contract in which it received \$5.97 billion in exchange for providing 300 million doses of the COVID-19 vaccine to the government.

## **B. Factual Background and Procedural History<sup>5</sup>**

Before his death, Isaiah was in good health, and although he had chronic asthma since childhood, it was well managed. In November 2021, Isaiah was “mandated, coerced, and fraudulently induced” to take a COVID-19 vaccine to “comply with one or more

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<sup>5</sup> This recitation of the facts is based upon the Estate’s second amended complaint. The Court recites only the facts pertinent to resolving the Defendants’ motions to dismiss. At this stage of the proceedings, for purposes of ruling on the motions, the facts alleged in the second amended complaint, and the reasonable inferences drawn therefrom, are set forth in the light most favorable to the Estate.

mandates, and to be able to work inside a Defendant hospital as an employee and/or intern.” (Doc. 127 at 5–6, paras. 13, 18). On November 23, 2021, Isaiah presented to the Baptist East emergency room with chest pain and shortness of breath. Isaiah eventually passed away in the emergency room. An expert physician has opined that Isaiah died “as the direct and proximate result of a vaccine injury.” (*Id.* at 6, para. 17). Specifically, Isaiah experienced a “vaccine-induced condition” called spontaneous pneumothorax. (*Id.* at 14, para. 64). The Estate alleges that COVID-19 vaccines are unreasonably dangerous; and that the Defendants failed to provide adequate warnings regarding the vaccines’ risks, falsely represented that the vaccines were safe and effective, concealed the vaccines’ known risks, and conspired to falsely represent the vaccines’ safety. Although the Estate does not bring a discrete claim that the PREP Act is unconstitutional, the SAC alleges that the PREP Act violates numerous constitutional provisions. The SAC also alleges that HHS “guaranteed in writing” that an enforcement action would never be initiated against Pfizer. (*Id.* at 14, para. 63).

The Pfizer Defendants are manufacturers of COVID-19 vaccines. (*E.g., id.* at 11, para. 49). Although the Estate alleges that there were three different COVID-19 vaccines available when Isaiah was vaccinated, (*see, e.g., id.* at 10, para. 45), the SAC does not identify which vaccine Isaiah received and does not allege that he received the Pfizer-BioNTech COVID-19 vaccine, (*see, e.g., id.* at 5–6, paras. 11, 22; 13, para. 61).<sup>6</sup> The Baptist Health Defendants “exercised supervisory control over Isaiah [] during his

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<sup>6</sup> In addition to the Pfizer-BioNTech vaccine, there was a COVID-19 vaccine manufactured by Moderna and one manufactured by Johnson & Johnson.

internship and/or part-time employment.” (*Id.* at 3, para. 6). Thus, the Court construes the SAC to allege that Isaiah worked for (at least one of) the Baptist Health Defendants before he died, either as an employee or intern. The Federal Defendants were co-leaders of Operation Warp Speed, an initiative aimed at facilitating and accelerating the development and manufacture of COVID-19 vaccines.

The SAC asserts twelve Alabama state law claims. Count I, a claim under the Alabama Extended Manufacturer’s Liability Doctrine (“AEMLD”), is brought against the Federal Defendants and the Pfizer Defendants. The remaining eleven claims are brought against all Defendants: failure to warn (Count II); breach of warranty of merchantability (Count III); negligence (Count IV); wantonness (Count V); fraud—misrepresentation (Count VI); fraud—suppression (Count VII); invasion of privacy (Count VIII); battery (Count IX); breach of contract (Count X); conspiracy (Count XI); and wrongful death pursuant to ALA. CODE § 6-5-410 (Count XII).

## V. DISCUSSION

The Defendants move for dismissal of the entire SAC, raising a host of arguments; some arguments overlap, and some are specific to certain Defendants. While not an exhaustive accounting, the Court briefly summarizes their arguments. All Defendants argue that PREP Act immunity and preemption bar the Estate’s claims, and that the SAC remains an impermissible shotgun pleading.<sup>7</sup> Additionally, the Federal Defendants argue

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<sup>7</sup> The Court previously struck the Estate’s original complaint because it was a shotgun pleading and ordered the Estate to file an amended complaint which complied with the Federal Rules of Civil Procedure and the Court’s directives. (Doc. 101). The Estate filed an amended complaint (doc. 109), and it was later granted leave (doc. 117) to file a second amended complaint identifying the proper Defendants in the case.

that they are entitled to sovereign immunity. The Pfizer Defendants contend that the SAC fails to adequately allege that they caused Isaiah’s injuries because the SAC does not allege that Isaiah received a Pfizer-BioNTech vaccine. Finally, the Baptist Health Defendants argue that they are immune under Alabama law governing “health emergency” claims,<sup>8</sup> and that the Estate failed to comply with the pleading requirements of the Alabama Medical Liability Act, which they contend governs the SAC.

For the reasons explained further below, the Court concludes that PREP Act immunity shields the Defendants from suit and liability. Additionally, the claims against the Federal Defendants are due to be dismissed for the additional, independent reason that they are entitled to sovereign immunity. And the claims against the Pfizer Defendants are due to be dismissed for insufficient allegations of causation. The Court addresses each issue in turn below.

#### **A. PREP Act Immunity Bars the Estate’s Claims**

The Defendants argue that PREP Act immunity shields them from suit and liability for the Estate’s claims because they are “covered persons,” and the Estate’s claims arise out of the administration of a “covered countermeasure,” specifically a COVID-19 vaccine,

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<sup>8</sup> The Baptist Health Defendants raised this argument in its motion to dismiss the Estate’s original complaint (*see* doc. 29 at 7); in their motion to dismiss the SAC, they incorporated by reference all defenses and arguments raised in their previous motions to dismiss (*see* doc. 135 at 4–5). The Court strongly disfavors a party incorporating by reference arguments it made in an earlier filing because it requires the Court and the nonmoving party to toggle between multiple filings to determine what the relevant arguments are. This practice is burdensome, inefficient, and unnecessary given that the undersigned does not impose page limitations on filings. Moreover, the problem is exacerbated here because in their earlier motions to dismiss, the Baptist Health Defendants also incorporated by reference arguments made by other Defendants, some of whom are no longer parties to the case. The result is a Matryoshka doll of arguments which are unnecessarily burdensome to disaggregate.

for which the Secretary issued a PREP Act declaration. The Defendants also contend that the SAC fails to sufficiently allege facts supporting a willful misconduct claim, the sole exception to PREP Act immunity, and that the Estate also failed to comply with procedural requirements for bringing such a claim.

The Estate contests the applicability of PREP Act immunity, asserting that COVID-19 vaccines are not covered countermeasures, PREP Act immunity does not apply to wrongful death claims, and the Court should not apply PREP Act immunity in any event because the Act is unconstitutional in multiple respects. Additionally, in its responses in opposition to the Defendants' motions to dismiss, the Estate represents that it does not allege "willful misconduct" as defined by the PREP Act. (*See, e.g.*, doc. 136 at 4 ("Plaintiff in this case doesn't allege PREP-defined 'willful misconduct.'")); doc. 137 at 6 ("This case . . . doesn't allege willful misconduct."); doc. 138 at 22 ("Plaintiff in this case doesn't allege willful misconduct.")).

The Court begins with whether PREP Act immunity bars the Estate's claims. To start, COVID-19 vaccines, including the vaccines developed and manufactured by the Pfizer Defendants, plainly are "covered countermeasures." *See* 42 U.S.C. § 247d-6d(i)(1), (7); Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. at 15,202 (defining a covered countermeasure to include "any vaccine[] used to treat, diagnose, cure, prevent, or mitigate COVID-19"); *see also Caratini-Soto v. Puerto Rico*, 2023 WL 11196890, at \*6 (D.P.R. Dec. 28, 2023) (concluding that COVID-19 vaccines manufactured by Pfizer are "covered

countermeasures”).<sup>9</sup> The Estate resists this conclusion on the grounds that the vaccines were not authorized according to the requirements of the EUA statute and therefore do not qualify as “covered countermeasures.” Thus, the Estate effectively challenges the Secretary’s decision to issue an EUA for the Pfizer-BioNTech COVID-19 vaccine. But the Secretary’s decisions under the EUA statute are judicially unreviewable: the Secretary’s actions under the statute “are committed to agency discretion,” 21 U.S.C. § 360bbb-3(i), and the Administrative Procedure Act (“APA”—the vehicle by which a party may challenge agency action—expressly does not apply where “agency action is committed to agency discretion by law,” 5 U.S.C. § 701(a)(2); *see, e.g., Ass’n of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at \*3 (6th Cir. Sept. 24, 2020) (“[E]mergency-use authorizations are exempt from review under the APA.” (first citing 5 U.S.C. § 701(a)(2); then citing 21 U.S.C. § 360bbb-3(i))). Consequently, the Estate’s argument is unavailing, and the Court finds that COVID-19 vaccines are “covered countermeasures.”

All remaining conditions for PREP Act immunity to apply have been met: the Defendants are “covered persons,” the Secretary issued a PREP Act declaration with respect to COVID-19 vaccines, and the Estate’s claims are within the scope of the Act’s immunity coverage. The Court has little trouble concluding that all Defendants are “covered persons”; indeed, the Estate does not argue otherwise. The Federal Defendants are United States agencies and officers and thus “covered persons.” *See* 42 U.S.C. § 247d-

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<sup>9</sup> Here, and elsewhere in this Opinion, the Court cites nonbinding authority. While the Court acknowledges that these cases are nonprecedential, the Court finds them persuasive.

6d(i)(2). The Pfizer Defendants developed and manufactured COVID-19 vaccines; vaccine manufacturers are plainly “covered persons.” *See id.*; *see also Caratini-Soto*, 2023 WL 11196890 at \*6 (concluding that “Pfizer is a ‘covered person’ and the COVID-19 vaccines it developed and manufactured are a ‘covered counter measure’”); *Goins v. St. Elizabeth Med. Ctr.*, 640 F. Supp. 3d 745, 753 (E.D. Ky. 2022) (finding that Moderna, a COVID-19 vaccine manufacturer, was a “covered person under the PREP Act”). The Baptist Health Defendants are “program planners” and thus “covered persons” based on their alleged requirement that their employees and interns receive the COVID-19 vaccine. *See* 42 U.S.C. § 247d-6d(i)(2). And as indicated above, the Secretary issued a PREP Act declaration with respect to COVID-19 vaccines. Finally, the thrust of the Estate’s claims is that the COVID-19 vaccine administered to Isaiah was unsafe and caused his death, and that the Defendants are liable because they, for example, failed to warn Isaiah about the vaccine’s risks and falsely represented the vaccine’s safety. Thus, the Estate’s claims all arise out of, relate to, or result from the administration to Isaiah of a COVID-19 vaccine.

Therefore, except to the extent the Estate asserts a willful misconduct claim, the PREP Act immunity applies. But because the Estate affirmatively represents that it has not alleged willful misconduct, the Court pretermits discussion of whether the SAC adequately alleged it. Consequently, PREP Act immunity operates as a bar to the Estate’s claims. *See, e.g., Caratini-Soto*, 2023 WL 11196890, at \*6 (concluding that Pfizer was “immune from suit and liability” on the plaintiff’s claims because the claims arose out of Pfizer’s development and manufacture of COVID-19 vaccines).

Citing 42 U.S.C. § 247d-6d(d)(2), the Estate argues that PREP Act immunity does not apply to wrongful death claims. The Court disagrees. Recall that § 247d-6d(d)(1) sets forth “the sole exception” to PREP Act immunity: willful misconduct. Section 247d-6d(d)(2) states that “[a]n action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.” Considering § 247d-6d(d) as a whole, subsection (d)(2) plainly does not expand the “sole exception” to immunity—willful misconduct—laid out in subsection (d)(1). Rather, subsection (d)(2) simply specifies *who* can bring a willful misconduct action. Thus, the Court finds the Estate’s argument unavailing.

In further effort to avoid the applicability of PREP Act immunity, the Estate insists that the PREP Act is unconstitutional in multiple respects. According to the Estate, the PREP Act violates procedural due process, the Takings Clause, the Seventh Amendment, the Commerce Clause, and the nondelegation doctrine. The Estate also asserts that the CICP’s one-year statute of limitations for filing administrative claims is unconstitutional.

The PREP Act, like all federal statutes, enjoys a “presumption of constitutionality,” and a federal court may invalidate it “only upon a plain showing that Congress has exceeded its constitutional bounds.” *United States v. Morrison*, 529 U.S. 598, 607 (2000). Mindful of this presumption, the Court addresses each of the Estate’s constitutional arguments in turn.<sup>10</sup>

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<sup>10</sup> The Estate also conclusorily asserts that the PREP Act offends other constitutional provisions, including the Equal Protection Clause and the Privileges and Immunities Clause. However, the Estate fails to provide analysis or citation to authority, and the Court declines to formulate arguments on the Estate’s behalf. Cf. *Resol. Tr. Corp. v. Dunmar Corp.*, 43 F.3d 587, 599 (11th Cir. 1995) (en banc) (reviewing grant of summary judgment and explaining that “[t]here is no burden upon the district court to distill every potential argument

## 1. Procedural Due Process

The Estate contends that the PREP Act, through its immunity provisions, violates procedural due process by eliminating or severely limiting state law claims for damages arising out of vaccine injuries. According to the Estate, it has a protected property interest in its state law claims against the Defendants which the PREP Act has eliminated. The Defendants argue that the Estate lacks a protected property interest because its state law claims arose after the PREP Act was enacted, and in any event, Congress' legislative determination in passing the PREP Act afforded all the "process" that was due.

Before the government may deprive a person of life, liberty, or property, it must provide "notice and opportunity for hearing appropriate to the nature of the case." *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 313 (1950). Thus, the Court must determine whether the Estate was deprived of a protected interest and, if so, what process it was due. *See id.* In several cases, the United States Supreme Court has stated that a state cause of action is a property interest protected by the Due Process Clause. *See id.*; *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428–29 (1982) (stating that the *Mullane* Court held that "a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause" and reaffirming that holding); *see also Martinez v. State of Cal.*, 444 U.S. 277, 281–82 (1980) ("Arguably, the cause of action for wrongful

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that could be made based upon the materials before it"; instead, "the onus is upon the parties"). The Estate thus falls well short of making a "plain showing that Congress exceeded its constitutional bounds" on these bases.

death that the State [of California] has created is a species of ‘property’ protected by the Due Process Clause.”).

But the Supreme Court has also said that its cases have “clearly established that ‘[a] person has no property, no vested interest, in any rule of the common law.’” *Duke Power Co. v. Carolina Env’t Study Grp.*, 438 U.S. 59, 93 n.32 (1978) (alteration in original) (quoting *Mondou v. N.Y., N.H. & H.R. Co.*, 223 U.S. 1, 50 (1912)). Additionally, the former Fifth Circuit rejected a due process challenge to the Swine Flu Act because the plaintiffs’ state law cause of action against a vaccine manufacturer “did not arise until after passage of the Swine Flu Act” and thus did not deprive the plaintiffs of a “vested right.” *Ducharme v. Merrill-National Lab’ys*, 574 F.2d 1307, 1310 (5th Cir. 1978).<sup>11</sup> According to the Defendants, *Ducharme* supports the conclusion that the Estate lacks a protected property interest in its state law causes of action because they did not arise until after the PREP Act was enacted. *See id.* To the extent the statements about property interests in causes of action in *Logan*, *Duke Power*, and *Ducharme* conflict with one another, the Court need not resolve any conflict because even if the Estate had a protected property interest in its causes of action, its due process challenge still fails because, as explained further below, Congress’ “legislative determination provid[ed] all the process that [was] due.” *See Logan*, 455 U.S. at 433.

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<sup>11</sup> In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

Even where the Supreme Court has said state law causes of action are property interests, it has also explained that “the State remains free to create substantive defenses or immunities for use in adjudication—or to eliminate its statutorily created causes of action altogether[.]” *Id.* at 432. For example, where a state statute grants officials immunity from certain types of state tort claims, the grant of immunity arguably deprives plaintiffs of a protected property interest, but they are *not* deprived of property without due process because “the legislative determination provides all the process that is due.” *Id.* at 432–33. This case differs from *Logan* and its progeny because here, the PREP Act is a *federal* statute which supplies immunity from *state* law claims. Notwithstanding this difference, Congress’ legislative determination to provide immunity for certain state law claims “provide[d] all the process that [was] due.” *See id.* at 433. Therefore, assuming without deciding that the PREP Act deprived the Estate of a protected property interest, the Estate was not deprived of this interest without constitutionally adequate process. *See id.*

The Estate cites *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59, 93 (1978), for the proposition that “it is a violation of due process to extinguish and replace state and common law injury claims by an administrative compensation program unless that replacement program provides a reasonable, prompt, and equitable mechanism for compensating victims.” (*See* doc. 137 at 12). Put differently, the PREP Act offends due process because, according to the Estate, the CICP does not provide an adequate substitute remedy. But this proposition does not follow from *Duke Power*. *Duke Power* involved, as relevant here, a due process challenge to the Price-Anderson Act, 42 U.S.C. § 2210, which limited liability “for nuclear accidents resulting from the operation of private

nuclear power plants licensed by the Federal Government.” 438 U.S. at 62–63. The plaintiff objected to the liability limitation because, among other reasons, it “fail[ed] to provide those injured by a nuclear accident with a satisfactory *quid pro quo* for the common-law rights of recovery which the Act abrogates.” *Id.* at 87–88 (emphasis in original). The Supreme Court observed that it was “not at all clear that the Due Process Clause in fact requires that a legislatively enacted compensation scheme either duplicate the recovery at common law or provide a reasonable substitute remedy,” but the Court ultimately declined to resolve the question because it concluded that the Price-Anderson Act “provid[ed] a reasonably just substitute for the common-law or state tort law remedies it replaces.” *Id.* at 88. Thus, the Court concluded that the Price-Anderson Act did not violate due process. *Id.* at 94.

*Duke Power* did not uphold the challenged federal statute because it had an adequate substitute remedy; “it merely refused to strike the [statute] for lacking one, because it *did not lack one.*” *Schmidt v. Ramsey*, 860 F.3d 1038, 1049 (8th Cir. 2017) (emphasis in original). This Court “decline[s] to extend *Duke Power* to hold its inverse: that a statute violates due process when it curtails a common law remedy without providing a just substitute.” *Cf. id.* (rejecting a substantive due process challenge on this basis).<sup>12</sup> For these reasons, the Estate fails to establish that the PREP Act violates procedural due process.

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<sup>12</sup> The Court need not, and does not, decide whether the PREP Act provides an adequate substitute for the state tort law remedies it replaces.

## 2. Takings Clause

The Estate also argues that the PREP Act violates the Takings Clause because it takes away the Estate’s right to bring state law tort claims against vaccine manufacturers and distributors. The Fifth Amendment’s Takings Clause prevents the federal government “from depriving private persons of *vested* property rights except for a ‘public use’ and upon payment of ‘just compensation.’” *Landgraf v. USI Film Prods.*, 511 U.S. 244, 266 (1994) (emphasis added). According to the Estate, the Takings Clause may apply when a private person has not been deprived of physical property but instead when he or she has been deprived of a cause of action. In support, the Estate cites *Alliance of Descendants of Texas Land Grants v. United States*, 37 F.3d 1478, 1481 (Fed. Cir. 1994), where the claimants alleged that the United States, by entering into a treaty with Mexico, “took away [the claimants’] legal right to sue for compensation” for a taking of certain land. The court concluded that the claimants had sufficiently identified a compensable property interest under the Takings Clause “[b]ecause a legal cause of action is property within the meaning of the Fifth Amendment.” *Id.*

*Texas Land Grants* is not binding on this Court; in any event, the Court finds it inapposite because there, the claimants’ causes of action had already arisen before the treaty extinguished them; thus, the causes of action were a *vested* property right. Cf. *Landgraf*, 511 U.S. at 266. Here, by contrast, the Estate’s causes of action against the Defendants did not arise until 2021—well after Congress passed the PREP Act in 2005. Thus, assuming the Court found the reasoning in *Texas Land Grants* persuasive, the Court

finds it inapplicable in this situation. Consequently, the Estate fails to show that the PREP Act violates the Takings Clause.<sup>13</sup>

### **3. Seventh Amendment Right to a Jury Trial**

The Estate also contends that the PREP Act violates the Seventh Amendment right to a jury trial because “the CICP’s appellate review model . . . allow[s] an administrative agency to adjudicate what may be core private rights without a jury.” (*E.g.*, doc. 136 at 42–43). The Seventh Amendment provides that “[i]n Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved.” The Supreme Court “has construed this language to require a jury trial on the merits in those actions that are analogous to ‘Suits at common law.’” *Tull v. United States*, 481 U.S. 412, 417 (1987). “The phrase ‘Suits at common law’ has been construed to refer to cases tried prior to the adoption of the Seventh Amendment in courts of law in which jury trial was customary as distinguished from courts of equity or admiralty in which jury trial was not.” *Atlas Roofing Co. v. Occupational Safety & Health Rev. Comm’n*, 430 U.S. 442, 449 (1977).

The Estate asserts, with virtually no analysis, that the PREP Act violates the Seventh Amendment because it allows an agency “to adjudicate what *may* be core private rights without a jury.” (*E.g.*, doc. 136 at 42–43) (emphasis added). This assertion is insufficient

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<sup>13</sup> The Estate also argues that HHS’ purported written promise not to bring an enforcement action against the Pfizer Defendants results in an unconstitutional taking because, according to the Estate, it effectively abrogates the willful misconduct exception to PREP Act immunity. But as stated above, the Estate represents that it is *not* alleging willful misconduct, and the Pfizer Defendants have not sought dismissal based on this purported written agreement. For these reasons, the resolution of this issue would not impact the outcome in this case, and the Court pretermits further discussion of it.

to persuade the Court that the PREP Act poses a Seventh Amendment problem.<sup>14</sup> Moreover, with respect to the Federal Defendants, “the Seventh Amendment right to trial by jury does not apply in actions against the Federal Government.” *Lehman v. Nakshian*, 453 U.S. 156, 160 (1981). Because suits against the Federal Government require a legislative waiver of immunity, they “are not ‘suits at common law’ within the meaning of the Seventh Amendment.” *Glidden Co. v. Zdanok*, 370 U.S. 530, 572 (1962) (citing *McElrath v. United States*, 102 U.S. 426, 439–40 (1880)). For this additional reason, the PREP Act does not violate the Seventh Amendment with respect to the Estate’s claims against the Federal Defendants.

The Estate’s reliance on *Securities & Exchange Commission v. Jarkesy*, 603 U.S. 109 (2024), does not change the Court’s conclusion. In *Jarkesy*, the Supreme Court addressed “whether the Seventh Amendment entitles a defendant to a jury trial when the SEC seeks civil penalties against him for securities fraud.” 603 U.S. at 120. While the Court explained that “what matters is the substance of the suit, not where it is brought, who

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<sup>14</sup> For example, the Estate’s argument appears based on the premise that the PREP Act, and the CICP in particular, impermissibly abrogates the Estate’s right to a jury trial on its various state law causes of action. But the CICP is not a forum for adjudicating garden-variety state law claims; instead, the CICP provides compensation only for “covered injuries” (death or serious injury). See 42 C.F.R. § 110.3(g). In this respect, the Estate does not meaningfully address “the distinction between assigning common-law claims to a non-jury tribunal and creating novel statutory claims subject to administrative resolution.” *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 658 (S.D. Tex. 2004). To be sure, “[t]he Seventh Amendment extends to a particular statutory claim if the claim is ‘legal in nature.’” *Secs. & Exch. Comm’n v. Jarkesy*, 603 U.S. 109, 122 (2024) (quoting *Granfinanciera, S.A. v. Nordbreg*, 492 U.S. 33, 53 (1989)). But the Estate also does not meaningfully address whether the claims subject to the CICP are “legal in nature.” To determine whether a claim is legal in nature, courts “consider the cause of action and the remedy it provides,” with the remedy being “the ‘more important’ consideration.” *Id.* at 122–23 (quoting *Tull*, 481 U.S. at 421). “[M]onetary relief can be legal or equitable”; such relief is legal if it is “designed to punish and deter” and equitable if it merely compensates or “restore[s] the status quo.” *Id.* at 123–25 (quoting *Tull*, 481 U.S. at 422). The Estate does not address these considerations.

brings it, or how it is labeled,” *id.* at 135, the Court did not address a situation sufficiently analogous to that which is presented here: a federal statute that simultaneously (1) provides broad immunity for claims based on vaccine injuries and (2) sets up an administrative claims process by which a person may seek compensation, paid from the U.S. Treasury, if a vaccine caused serious injury or death. “When the United States abolishes a cause of action and then sets up a separate administrative remedy against itself, . . . the [S]eventh [A]mendment does not require that it must also provide a jury trial.” *Hammond v. United States*, 786 F.2d 8, 15 (1st Cir. 1986). Additionally, the *Jarkesy* Court did not overrule its precedents holding that there is no Seventh Amendment right to a jury trial in an action against the federal government. For these reasons, the Court finds the Estate’s Seventh Amendment challenge unavailing.

#### **4. Commerce Clause**

The Estate also argues that the PREP Act violates the Commerce Clause because it regulates activities that are not “inherently economic or commercial.” (*E.g.*, doc. 136 at 46). It contends that the Act is infirm because it “contains no express jurisdictional limitations that constrain its reach to circumstances where the activities it regulates in fact affect interstate commerce.” (*Id.* at 47). In support, the Estate cites *United States v. Lopez*, 514 U.S. 549 (1995), and *Morrison*, 529 U.S. 598, two cases in which the Supreme Court held that Congress exceeded its Commerce Clause power.

The Constitution grants Congress the power “[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.” U.S. CONST. art. I, § 8, cl. 3. “The commerce power—that is, the combination of the Commerce Clause per se and

the Necessary and Proper Clause—encompasses authority to regulate three categories of activities.” *Garcia v. Vanguard Car Rental USA, Inc.*, 540 F.3d 1242, 1249 (11th Cir. 2008). The Commerce Clause confers upon Congress the authority to (1) “regulate the use of the channels of interstate commerce” and (2) “to regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities.” *Morrison*, 529 U.S. at 609 (citations omitted). Third and finally, Congress has the power to regulate “those activities that substantially affect interstate commerce.” *Lopez*, 514 U.S. at 559. “Where economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.” *Id.* Because the parties focus on the “substantial effects” category, the Court will do the same.<sup>15</sup>

In *Lopez*, the Supreme Court held that the Gun-Free School Zones Act of 1990 exceeded Congress’ commerce authority because it did not regulate an activity which substantially affects interstate commerce. 514 U.S. at 551. The Court explained that the statute, which made it a federal crime to knowingly possess a firearm in a school zone, “by its terms ha[d] nothing to do with ‘commerce’ or any sort of economic enterprise,” and also that it “contain[ed] no jurisdictional element which would ensure, through case-by-case inquiry, that the firearm possession in question affect[ed] interstate commerce.” *Id.* at 561; *see also id.* at 567 (“The possession of a gun in a local school zone is in no sense an

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<sup>15</sup> Because the Court concludes that the PREP Act permissibly regulates “those activities that substantially affect interstate commerce,” *Lopez*, 514 U.S. at 559, the Court need not, and does not, decide whether the PREP Act also fits within either or both of the other two categories.

economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce.”). The Court further observed that there were no legislative findings regarding the effect on interstate commerce of gun possession in a school zone. *Id.* at 562. The Court acknowledged that “Congress normally is not required to make formal findings as to the substantial burdens that an activity has on interstate commerce.” *Id.* But the Court confirmed that legislative findings are relevant to the “evaluation of constitutionality under the Commerce Clause,” *id.*, and merely observed that the lack of findings did not assist the Court in ascertaining “the legislative judgment that the activity in question substantially affected interstate commerce,” *id.* at 563.

In *Morrison*, the Court invalidated the federal civil remedy provided in the Violence Against Women Act of 1994 (“VAWA”) because it exceeded Congress’ commerce authority. 529 U.S. at 601–02. The Court reasoned that “[g]ender-motivated crimes of violence are not, in any sense of the phrase, economic activity” and that the statute contained “no jurisdictional element establishing that the federal cause of action is in pursuance of Congress’ power to regulate interstate commerce.” *Id.* at 613. Although Congress had found that gender-motivated violence affects interstate commerce, the Court determined the congressional findings were insufficient to sustain VAWA because the causal chain linking occurrences of gender-motivated violence to effects on interstate commerce was too attenuated. *Id.* at 615; *see also id.* at 614 (“[T]he existence of congressional findings is not sufficient, by itself, to sustain the constitutionality of Commerce Clause legislation.”).

The PREP Act regulates economic activity which substantially affects interstate commerce in a way the statutes at issue in *Lopez* and *Morrison* did not. The Court has little trouble concluding that declaring a public health emergency—an action the PREP Act authorizes—has a substantial effect on interstate commerce by, for example, disrupting employment, shipping, and manufacturing nationwide. Moreover, Congress passed the PREP Act to encourage, during public health emergencies, the manufacture and distribution of medical countermeasures such as vaccines by limiting liability relating to their administration. *See 42 U.S.C. § 247d-6d(a)(1), (b)(1)*. Unlike gun possession in a school zone or gender-motivated violence, the manufacture and distribution of “covered countermeasures” are economic activities. And the PREP Act facilitates interstate commerce by removing the specter of liability under every state’s tort law relating to these economic activities. *See Garcia*, 540 F.3d at 1252 (“[I]t has long been understood that the commerce power includes not only the ability to regulate interstate markets, but the ability to facilitate interstate commerce by removing intrastate burdens and obstructions to it.”); *cf. Duke Power*, 438 U.S. at 83–84 (concluding that the Price-Anderson Act, which limited liability “for nuclear accidents resulting from the operation of private nuclear power plants licensed by the Federal Government,” was a “classic example of an economic regulation—a legislative effort to structure and accommodate the ‘burdens and benefits of economic

life”” (citation omitted)).<sup>16</sup> Because the PREP Act regulates economic activity, “*Lopez* and *Morrison* are inapposite.” *Garcia*, 540 F.3d at 1252.

The Court is also not persuaded that the PREP Act exceeds Congress’ Commerce Clause power on the grounds that it “contains no express jurisdictional limitations” and “lacks any express legislative findings that the non-economic intrastate activities have any effects on interstate commerce,” (*see doc.* 136 at 47). Because the PREP Act “regulates a class of activities that substantially affects interstate commerce,” it does not matter that the Act lacks a jurisdictional limitation and legislative findings. *See United States v. Olin Corp.*, 107 F.3d 1506, 1510 (11th Cir. 1997) (“[W]e conclude that although Congress did not include in [the statute] either legislative findings or a jurisdictional element, the statute remains valid as applied in this case because it regulates a class of activities that substantially affects interstate commerce.”); *see also id.* (interpreting *Lopez* as “recogniz[ing] that a statute without a jurisdictional element still would stand under the Commerce Clause, if the law satisfied the substantial effects test”). For these reasons, the Court concludes that the PREP Act does not exceed Congress’ Commerce Clause power.<sup>17</sup>

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<sup>16</sup> *Duke Power* did not involve a Commerce Clause challenge, and this statement about economic regulation was made regarding the petitioners’ due process challenge; however, *Duke Power*’s reasoning bolsters the Court’s conclusion that the PREP Act regulates economic activity.

<sup>17</sup> The Court construes the Estate’s invocations of the Ninth Amendment, the Tenth Amendment, and the Necessary and Proper Clause as part and parcel of its argument regarding the Commerce Clause. *See, e.g., Garcia*, 540 F.3d at 1249 (observing that the Commerce Clause and the Necessary and Proper Clause together confer upon Congress the authority to regulate commerce). In any event, the Estate does not sufficiently explain why, in its view, the PREP Act violates the Ninth Amendment, which provides: “The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.” Additionally, the PREP Act does not violate the Tenth Amendment because the Constitution delegates to Congress, in Article I, the power to regulate interstate commerce; therefore, such power is not one which the Constitution “reserved to the States.” *See U.S. CONST. amend. X* (“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the

## 5. Nondelegation Doctrine and Separation of Powers

The Estate also argues that the PREP Act violates the nondelegation doctrine because it gives the Secretary unfettered discretion to declare a public health emergency and effectively nullify, through immunity, most state law causes of action.

“The nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government.” *Mistretta v. United States*, 488 U.S. 361, 371 (1989). Article I of the Constitution provides that “[a]ll legislative Powers herein granted shall be vested in a Congress of the United States.” U.S. CONST. art. I, cl. 1. “[T]he integrity and maintenance of the system of government ordained by the Constitution” mandate that Congress generally cannot delegate its legislative power to another Branch.” *Mistretta*, 488 U.S. at 371–72 (quoting *Field v. Clark*, 143 U.S. 649, 692 (1892)). Congress may, however, “obtain[] the assistance of its coordinate Branches.” *Id.* at 372. Congress may also “‘vest[] discretion’ in executive agencies to implement and apply the laws it has enacted—for example, by deciding on ‘the details of [their] execution.’” *Fed. Commc’ns Comm’n v. Consumers’ Rsch.*, 145 S. Ct. 2482, 2496–97 (U.S. June 27, 2025) (alterations in original) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928)).

“Congress may delegate authority to a coordinate branch when it lays ‘down by legislative act *an intelligible principle* to which the person or body authorized to [exercise the delegated authority] is directed to conform.’” *United States v. Brown*, 364 F.3d 1266,

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States respectively, or to the people.”); *see also United States v. Comstock*, 560 U.S. 126, 144 (2010) (“The powers ‘delegated to the United States by the Constitution’ include those specifically enumerated powers listed in Article I along with the implementation authority granted by the Necessary and Proper Clause. Virtually by definition, these powers are not powers that the Constitution ‘reserved to the States.’”).

1270 (11th Cir. 2004) (alteration and emphasis in original) (quoting *Mistretta*, 488 U.S. at 372). Congress articulates an intelligible principle if it “clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority.” *Mistretta*, 488 U.S. at 372–73. If Congress provides an intelligible principle to guide agency action, it effects a lawful grant of discretion rather than an unlawful delegation of legislative authority. *See J.W. Hampton*, 276 U.S. at 409. Although “the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred,” *Whitman v. Am. Trucking Assocs.*, 531 U.S. 457, 475 (2001), “[t]he government does not bear an onerous burden in demonstrating the existence of an intelligible principle,” *Brown*, 364 F.3d at 1271.

The Supreme Court has only twice invalidated a federal statute on nondelegation grounds: in a pair of 1935 cases, *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). *See Consumers' Rsch.*, 145 S. Ct. at 2502–03 (making this observation). In *Panama Refining*, “the statute empowered the President to bar the transport of petroleum products while ‘establish[ing] no [standard]’ and ‘declar[ing] no policy’ for whether, when, or how he should do so.” *Id.* (first and third alterations in original) (quoting *Panama Refining*, 293 U.S. at 430). The statute at issue in *Schechter Poultry*, which the Supreme Court described as “even worse,” *id.* at 2503, authorized the President “to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring ‘fair competition,’” *Whitman*, 531 U.S. at 474; *see also Consumers' Rsch.*, 145 S. Ct. at 2503. But since 1935,

and as recently as three months ago, *see generally Consumers' Rsch.*, 145 S. Ct. 2482,<sup>18</sup> the Supreme Court has rebuffed each nondelegation challenge lodged against an Act of Congress. Indeed, the Supreme Court has “found intelligible principles in a host of statutes giving agencies significant discretion,” including, among others, “a provision enabling an agency to set air quality standards at levels ‘requisite to protect the public health,’” and “a delegation to an agency to ensure that corporate structures did not ‘unfairly or inequitably distribute voting power’ among security holders.” *Consumers' Rsch.*, 145 S. Ct. at 2503 (first citing *Whitman*, 541 U.S. at 472; then citing *Am. Power & Light v. Sec. & Exch. Comm'n*, 329 U.S. 90, 104 (1946)).

The PREP Act fits comfortably alongside the federal statutes which have been upheld as lawful grants of discretion. The Estate does not dispute (*see doc. 137 at 47*) that Congress passed the PREP Act to encourage, by providing a liability shield, the rapid development and manufacture of drugs and biological products aimed at countering public health threats. Thus, the first requirement—that Congress “clearly delineate[] [a] general policy”—is satisfied. *See Mistretta*, 488 U.S. at 372–73. Congress itself determined the terms and scope of PREP Act immunity, including who is entitled to the immunity (“covered persons”), what the immunity covers (“all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered

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<sup>18</sup> In its briefing, the Estate highlights a 2024 Fifth Circuit case holding that Congress, in the Telecommunications Act, delegated legislative authority to the Federal Communications Commission to pursue “universal service.” (*See, e.g.*, doc. 136 at 49 (citing *Consumers Rsch. v. Fed. Commc'n's Comm'n*, 109 F.4th 743, 759 (5th Cir. 2024) (en banc))). But the Supreme Court recently reversed the Fifth Circuit and concluded that the statute did not violate the nondelegation doctrine. *See generally Consumers' Rsch.*, 145 S. Ct. 2482. Consequently, the now-reversed Fifth Circuit decision does not help the Estate establish a constitutional violation.

countermeasure”), and an exception to said immunity (willful misconduct resulting in serious injury or death). Congress delegated to the Secretary of the Department of Health and Human Services—and thus clearly identified “the public agency which is to apply” the general policy—the authority to determine that a disease, “other health condition,” or “other threat to health” is a “public health emergency,” or poses a “credible risk” of a future emergency; to “make a declaration recommending . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures”; and to state “that [the PREP Act’s immunity provision] is in effect with respect to th[ose] activities.” 42 U.S.C. § 247d-6d(b)(1). The PREP Act specifies when the Secretary should issue a PREP Act declaration: when he or she determines that a disease, “other health condition,” or “other threat to health” is a “public health emergency,” or poses a “credible risk” of a future emergency. *Id.* § 247d-6d(b)(1). The Act further directs the Secretary, in deciding whether to issue a PREP Act declaration, to consider “the desirability of encouraging” the development, testing, manufacture, administration, and use of countermeasures. *Id.* § 247d-6d(b)(6).

Additionally, the Secretary must include several pieces of information in the PREP Act declaration, including the particular disease, health condition, or threat to health triggering the Secretary’s recommendation; when the declaration is in effect; and to which individuals the declaration applies and where. *Id.* § 247d-6d(b)(2). Within thirty days of issuing a PREP Act declaration, the Secretary must submit a report to “the appropriate committees of the Congress” explaining his or her reasons for issuing the declaration and for deciding the timeframe, geographical scope, and other criteria set forth in § 247d-

6d(b)(2). *Id.* § 247d-6d(b)(9). The Secretary may amend a PREP Act declaration through publication in the Federal Register, *id.* § 247d-6d(b)(4), and he or she must submit a report within thirty days of the amendment explaining the reasons for it, *id.* § 247d-6d(b)(9). These provisions, considered together, support a finding that Congress also “clearly delineated . . . the boundaries of th[e] delegated authority.” *See Mistretta*, 488 U.S. at 372–73.

The Estate insists that because the PREP Act neither defines “public health emergency” nor provides a time limit on how long a PREP Act declaration may be in effect, the Act affords the Secretary too much discretion and effectively permits the Secretary to issue an indefinite declaration impacting the national economy. That Congress did not provide precise criteria and permits the Secretary to exercise some degree of discretion is not fatal. For example, in *Whitman*, the Supreme Court rejected a nondelegation challenge to the Clean Air Act (“CAA”), which instructed the Environmental Protection Agency “to set primary ambient air quality standards ‘the attainment and maintenance of which . . . are requisite to protect the public health.’” 531 U.S. at 465 (alteration in original) (quoting 42 U.S.C. § 7409(b)(1)). The Court considered and rejected the petitioners’ argument that the CAA violated the nondelegation doctrine on the grounds that it afforded the agency too much discretion to determine what was “requisite.” *See id.* 475–76. The Court explained that it had never demanded “that statutes provide a ‘determinate criterion’ for saying ‘how much [of the regulated harm] is too much.’” *Id.* at 475 (alteration in original) (citation omitted). Among other cases, the Court highlighted its decision in *Lichter v. United States*, 334 U.S. 742 (1948), where it upheld a statute authorizing agencies to recoup “excess

profits” paid under certain government contracts without “insist[ing] that Congress specify how much profit was too much.” *Id.* (citing *Lichter*, 334 U.S. at 783–86).

“Congress is not confined to that method of executing its policy which involves the least possible delegation of discretion to administrative officers.” *Mistretta*, 361 U.S. at 379 (quoting *Yakus v. United States*, 321 U.S. 414, 425–26 (1944)); *see also Consumers’ Rsch.*, 145 S. Ct. at 2506 (“A ‘degree of policy judgment . . . can be left to those executing or applying the law.’” (quoting *Whitman*, 531 U.S. at 474–75)). Considering these precedents, the Court concludes that the PREP Act permissibly confers upon the Secretary the authority to determine that a “disease,” “other health condition,” or “other threat to health constitutes a public health emergency.” Similarly, the lack of a time limit on when a PREP Act declaration can be in effect does not render the Act constitutionally infirm.

The Estate’s other arguments for why the PREP Act is an impermissible delegation fail to move the needle. It asserts that the PREP Act is unconstitutional because it bars judicial review of the Secretary’s actions, and it contends that the required reports to Congress are no salve because the Act does not specify Congress’ role in providing feedback or responding to the reports. The Estate fails to cite caselaw from the Supreme Court or the Eleventh Circuit holding that a federal statute violated the nondelegation doctrine on any of these bases, and the Estate otherwise fails to adequately explain how these alleged deficiencies render the PREP Act constitutionally suspect. Consequently, the Estate has failed to make a “plain showing that Congress has exceeded its constitutional bounds.” *See Morrison*, 529 U.S. at 607.

## 6. CICP's Statute of Limitations

The Court concludes the tour of constitutional challenges with the Estate's objection to the CICP's statute of limitations. The Estate argues that “[t]he one-year CICP statute of limitations is arbitrary and capricious, irrational, and it impermissibly treats persons injured or killed by experimental COVID-19 shots worse than persons injured or killed by other vaccines who are allowed a two-year statute of limitations.” (Doc. 136 at 17; doc. 137 at 14). The Estate cites no authority in support of its argument that the one-year statute of limitations is arbitrary or irrational. And the PREP Act is not the only federal statute which imposes a one-year filing deadline. *See, e.g.*, 28 U.S.C. § 2244(d)(1) (provision in the Antiterrorism and Effective Death Penalty Act of 1996 applying a “1-year period of limitation . . . to an application for a writ of habeas corpus by a person in custody pursuant to the judgment of a State court”). Moreover, the Estate's contention that CICP claims related to COVID-19 vaccines are treated worse than CICP claims related to other vaccines rests on a flawed premise because *all* CICP claims for compensation are subject to a one-year statute of limitations. *See* 42 C.F.R. § 110.42(a) (providing that requests for compensation must be filed “within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury”). Consequently, the Estate has not shown that the PREP Act is unconstitutional because of the CICP's one-year statute of limitations.

## 7. Conclusion

When it passed the PREP Act, Congress made the policy choice that the benefits of providing broad immunity— incentivizing the production of medical countermeasures

during a public health emergency—outweighed the burdens, namely curtailing putative victims' recovery under state and federal law. While one may disagree with that policy decision, that does not mean the PREP Act is unconstitutional. The Court is sympathetic to the Estate's efforts to recover for Isaiah's death. Nonetheless, the Court is persuaded that its claims fail as a matter of law based on PREP Act immunity, and the SAC is due to be dismissed with prejudice for this reason alone.<sup>19</sup>

## **B. Alternative Grounds for Dismissal**

Even if the PREP Act did not bar the Estate's claims, the SAC is nonetheless due to be dismissed (1) as to the Federal Defendants, because they are entitled to sovereign immunity; and (2) as to the Pfizer Defendants, because the SAC does not sufficiently allege that they caused Isaiah's death.<sup>20</sup>

As a threshold matter, the Court addresses the Defendants' argument that Count XII (wrongful death pursuant to ALA. CODE § 6-5-410(a)) is the only cause of action the Estate can maintain under Alabama's survivorship and wrongful death statutes. *See* ALA. CODE § 6-5-410(a) (wrongful death); *id.* § 6-5-462 (survivorship). Though their arguments vary slightly, the Defendants essentially argue that (1) neither a breach of contract nor a breach of warranty can support a wrongful death claim; and (2) because Alabama recognizes only one cause of action for wrongful death, the remaining torts claims are not separately cognizable claims but instead variations of the legal theory underlying the Estate's

<sup>19</sup> Because the Court concludes that the Defendants are immune under the PREP Act, the Court in its discretion pretermits discussion of whether the PREP Act also preempts the Estate's claims.

<sup>20</sup> Because the Court concludes that the SAC is due to be dismissed for the reasons discussed in this Opinion, the Court pretermits discussion of the other grounds for dismissal raised by the Defendants.

wrongful death claim—or alternatively, they are unfiled tort claims that did not survive Isaiah’s death. The Estate did not respond to these arguments. Because the Estate did not respond, the Estate has effectively abandoned its claims except for Count XII (wrongful death). *See Collins v. Davol, Inc.*, 56 F. Supp. 3d 1222, 1228 (N.D. Ala. 2014) (concluding, at the motion to dismiss stage, that the plaintiff’s failure to respond to an argument that a claim should be dismissed constitutes abandonment of the claim, and the claim was due to be dismissed “on those grounds alone”).<sup>21</sup> Consequently, except for Count XII, all claims in the SAC are due to be dismissed as incompatible with Alabama’s wrongful death and survivorship statutes.

With only the Estate’s wrongful death claim (Count XII) remaining, the Court next addresses why this claim cannot survive dismissal as to the Federal Defendants and the Pfizer Defendants (assuming the PREP Act did not bar the claim, which the Court concludes it does).

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<sup>21</sup> Even if the Estate had not abandoned its non-wrongful-death claims, they are still due to be dismissed on the merits. Neither a breach of contract nor a breach of warranty can support a wrongful death claim. *See Geohagan v. Gen. Motors Corp.*, 279 So. 2d 436, 438–39 (Ala. 1973); *Ala. Powersports Auction, LLC v. Wiese*, 143 So. 3d 713, 717 (Ala. 2013) (confirming that *Geohagan* remains controlling law). As for the tort claims, the SAC alleges in each claim (except invasion of privacy) that the Defendants caused Isaiah’s death. (*See* doc. 127 at 16, para. 70 (AEMLD); 19, para. 93 (negligence); 21, para. 104 (wantonness); 29–30, paras. 125, 129 (fraudulent misrepresentation); 32, paras. 135, 139 (fraudulent suppression); 33, para. 147 (battery); 34, para. 152 (breach of contract); 35, para. 155 (conspiracy)). For this reason, the Court agrees that these claims are merely variations on the legal theory underlying the Estate’s claim pursuant to ALA. CODE § 6-5-410 (Count XII)—Alabama’s “one cause of action for wrongful death.” *Ala. Power Co. v. White*, 377 So. 2d 930, 933 (Ala. 1979); *see also Sledge v. IC Corp.*, 47 So. 3d 243, 247 (Ala. 2010). Finally, the Estate’s invasion of privacy claim, which rests on the theory that requiring Isaiah to receive a COVID-19 vaccine violated his bodily integrity, is an unfiled tort claim which did not survive Isaiah’s death. *See Bassie v. Obstetrics & Gynecology Assocs. of Nw. Ala., P.C.*, 828 So. 2d 280, 282 (Ala. 2002).

## 1. The Federal Defendants Are Entitled to Sovereign Immunity

The Estate cannot maintain its wrongful death claim against the Federal Defendants because they are entitled to sovereign immunity. Absent a waiver, the United States enjoys sovereign immunity from suits seeking money damages.<sup>22</sup> *Dep’t of Agric. Rural Dev. Rural Hous. Serv. v. Kirtz*, 601 U.S. 42, 48 (2024). The United States’ immunity “extends to its agencies,” *Asociation de Empleados del Area Canalera v. Panama Canal Comm’n*, 453 F.3d 1309, 1315 (11th Cir. 2006) (citing *FDIC v. Meyer*, 510 U.S. 471, 475 (1994)), as well as to “the employees of those agencies sued in their official capacities,” *Ishler v. Internal Revenue*, 237 F. App’x 394, 397 (11th Cir. 2007) (per curiam).<sup>23</sup> “A waiver of the Federal Government’s sovereign immunity must be unequivocally expressed in statutory text and will not be implied.” *Lane v. Pena*, 518 U.S. 187, 192 (1996); *see also Kirtz*, 601 U.S. at 48 (explaining that a suit against the government is permitted “only when a statute ‘unmistakabl[y]’ allows it” (alteration in original) (quoting *FAA v. Cooper*, 566 U.S. 284, 291 (2012))).

The Estate asserts that the PREP Act waives sovereign immunity because the United States and its agencies are “covered persons” under the PREP Act. But rather than waive sovereign immunity, the PREP Act expressly preserves it. *See* 42 U.S.C. § 247d-6d(f) (“Nothing in this section shall be construed . . . to waive sovereign immunity . . . .”). That

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<sup>22</sup> In a wrongful death action, “the only recoverable damages are punitive damages.” *Trott v. Brinks, Inc.*, 972 So. 2d 81, 84 (Ala. 2007).

<sup>23</sup> Indeed, “official-capacity suits ‘generally represent only another way of pleading an action against an entity of which an officer is an agent.’” *Hafer v. Melo*, 502 U.S. 21, 25 (1991) (quoting *Kentucky v. Graham*, 473 U.S. 159, 165 (1985)).

the United States are “covered persons” is insufficient to overcome either the general presumption that sovereign immunity applies or the PREP Act’s plain language preserving said immunity.

The Estate also argues that the Court should sever the PREP Act’s sovereign immunity provision from the statute because, according to the Estate, applying sovereign immunity would result in an unconstitutional taking in violation of the Fifth Amendment. This argument is misplaced. Sovereign immunity applies not solely (or primarily) because the PREP Act says so; rather, it applies because as a general rule, sovereign immunity shields the United States and its agencies from suit. Thus, even if the Court severed the PREP Act’s express preservation of sovereign immunity, the Federal Defendants would still be entitled to immunity because Congress did not unequivocally waive it in the PREP Act. Moreover, the Estate’s argument that sovereign immunity offends the Takings Clause fails for the same reasons discussed above regarding why the PREP Act does not violate the Takings Clause. *See supra* at 20–21. For these reasons, the Court concludes that sovereign immunity bars the wrongful death claim against the Federal Defendants.<sup>24</sup>

## **2. The SAC Does Not Adequately Allege that the Pfizer Defendants Caused Isaiah’s Death**

The wrongful death claim against the Pfizer Defendants is due to be dismissed because the Estate fails to sufficiently allege that the Pfizer Defendants caused Isaiah’s

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<sup>24</sup> Citing a law review article, the Estate also appears to argue that sovereign immunity should be eliminated. (Doc. 136 at 8 (citing ERWIN CHEMERINSKY, *Against Sovereign Immunity*, 53 STAN. L. REV. 1201, 1205 (2001)). But as the Federal Defendants correctly point out, “arguments made in a law review article are not the law.” (Doc. 139 at 11). This Court is bound to follow United States Supreme Court and Eleventh Circuit precedent, and precedent is clear that, absent a waiver, the federal government enjoys sovereign immunity.

death. Causation is an essential element of a wrongful death claim under Alabama law. *See ALA. CODE § 6-5-410(a)* (authorizing claim “whereby the death of the testator or intestate was caused” by a defendant’s misconduct (emphasis added)); *Hobson v. Bibb Cnty. Comm’n*, 2008 WL 11424253, at \*4 (N.D. Ala. Mar. 5, 2008) (stating that causation is an element of a wrongful death claim); *see also Hughes v. Marley*, 390 So. 3d 545, 549 (Ala. 2023) (“In a wrongful-death action predicated on theories of negligence and wantonness, a plaintiff must establish that the defendant’s tortious conduct proximately caused the decedent’s death.”).

As stated above, the SAC does not allege which vaccine was administered to Isaiah, and it does not allege that it was a Pfizer-BioNTech vaccine. Although the SAC alleges that the Pfizer Defendants “are liable for the harm caused by their vaccine and by their actions to fraudulently induce compliance with vaccine mandates through any of the authorized products,” (doc. 127 at 12–13, para. 58), this allegation is a legal conclusion which this Court need not accept as true. And without sufficient allegations that Isaiah took *the Pfizer Defendants’ vaccine*, the SAC does not plausibly allege that the Pfizer Defendants caused Isaiah’s death. Aside from restating the SAC’s allegations and listing the elements of a wrongful death claim under Alabama law (*see doc. 137 at 31–37*), the Estate did not respond to the Pfizer Defendants’ argument and did not cite authority supporting a theory of causation under which the Pfizer Defendants could be held liable. For these reasons, the wrongful death claim against the Pfizer Defendants is due to be

dismissed for the additional, independent reason that it fails to state a claim upon which relief can be granted.<sup>25</sup>

## VI. CONCLUSION

Accordingly, for the reasons stated, it is

ORDERED that the Defendants' motions to dismiss (docs. 132, 133, 135) are GRANTED as set forth herein, and the SAC is DISMISSED with prejudice.

A separate Final Judgment will be entered.

DONE this 23rd day of September, 2025.

/s/ Emily C. Marks

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EMILY C. MARKS  
CHIEF UNITED STATES DISTRICT JUDGE

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<sup>25</sup> In its response briefs, the Estate alternatively requests leave to amend its complaint. (*See, e.g.*, doc. 137 at 69). To the extent this embedded request should be construed as a motion for leave to amend the complaint, it fails to comply with Local Rule 15.1 because it did not attach a copy of the proposed amended pleading. And on this record, the Court finds that leave is not warranted under Rule 15 because further amendment would be futile. While the Court “should freely give leave [to amend] where justice so requires,” FED. R. CIV. P. 15(a)(2), the Court may deny leave if amendment would be futile. *L.S. ex rel. Hernandez v. Peterson*, 982 F.3d 1323, 1332 (11th Cir. 2020). The Court cannot imagine a scenario in which the Estate pleads claims that are not barred by PREP Act immunity. Leave is also not appropriate because the Estate has inexcusably failed to cure its defective pleadings in prior amendments. *See Foman v. Davis*, 371 U.S. 178, 182 (1962). Consequently, the Estate’s alternative request for leave to amend is denied.